

Section 1: 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment	Siemens Medical Solutions. Inc. 51 Valley Stream Parkway Malvern. PA 19355
Registration Number	2240869
Manufacturer	Siemens AG. Bereich Med Henkestrasse 127 D-91052 Erlangen. Germany
Registration Number	8010024
Contact Person	Ms. Judy Campbell Technical Specialist, Regulatory Submissions 51 Valley Stream Parkway Malvern. PA 19355 Phone: (610)448-4918 Fax: (610) 448-1787
Device Name	Trade Name: MAGNETOM Systems with Software <i>syngo</i> MR2006A
Classification Name:	Magnetic Resonance Diagnostic Device
CFR Section:	21 CFR § 892.1000
Classification:	Class II

Performance Standards

None established under Section 514 the Food, Drug, and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

The MAGNETOM Systems with the *syngo* MR2006A are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

The *syngo* MR2006A (VB13A) software upgrade will be available for the following MAGNETOM Family systems:

- The MAGNETOM 1.5 Telsa Avanto system with *syngo* MR2004V was described in premarket notification K032428 which received FDA clearance October 16, 2003.
- The MAGNETOM 1.5 Telsa Espree system with *syngo* MR2005E was described in premarket notification K041112 which received FDA clearance July 21, 2004.
- The MAGNETOM 1.5 Telsa Symphony a Tim System with *syngo* MR2006T was described in premarket notification K050199 which received FDA clearance February 18, 2005.
- The MAGNETOM 3 Telsa Trio a Tim System with *syngo* 2006T was described in premarket notification K050200 which received FDA clearance February 28, 2005.

Siemens Medical Solutions, Inc., intends to offer a software and hardware upgrade *syngo* MR2006A. The indications for use will stay exactly the same, with respect to the previous software versions mentioned in the comparison matrix.

Substantial Equivalence

The systems 1.5 T MAGNETOM Espree, Avanto, Symphony a Tim System and the 3 T MAGNETOM Trio a Tim System with *syngo* MR2006A are substantially equivalent to the following cleared medical devices:

<i>Predicate Device Name</i>	<i>FDA Clearance Number</i>	<i>FDA Clearance Date</i>
Siemens MAGNETOM 1.5 T Avanto	K032428	10/16/03
Siemens MAGNETOM 1.5 T Espree	K041112	July 21, 2004
Siemens MAGNETOM 1.5 T Symphony a Tim System	K050199	February 18, 2005
Siemens MAGNETOM 3 T Trio a Tim System	K050200	February 28, 2005

General Safety and Effectiveness Concerns:

The introduction of the new *syngo* MR2006A has no significant effect on the MR safety and performance parameters.

Siemens Medical Solutions is adding an upgrade in software and hardware to the currently available MAGNETOM Systems. The MRI systems are exactly the same as those described and cleared in the predicate device premarket notifications. Various safety and performance testing was completed; however the values are not significantly changed and, in the case of safety parameters remain below the level of concern.

The MAGNETOM Systems will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the international IEC standard for safety issues with Magnetic Resonance Imaging Devices. This will assure that the performance of this device can be considered safe and effective with respect to the currently available MAGNETOM systems.



OCT 4 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Judith Campbell
Technical Specialist
Siemens Medical Solutions, USA, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K052164
Trade/Device Name: MAGNETOM Systems with
Software *syngo* MR 2006A
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance
diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 8, 2005
Received: August 9, 2005

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K052164

Section 3: Indications for Use Statement

Device Name:

MAGNETOM Symphony a Tim System	510(k) Number (if known)	K050199
MAGNETOM Trio a Tim System	510(k) Number (if known)	K050200
MAGNETOM Espree	510(k) Number (if known)	K041112
MAGNETOM Avanto	510(k) Number (if known)	K032428

Indications for Use:

- The "MAGNETOM Espree"
- the "MAGNETOM Avanto"
- the "MAGNETOM Symphony a Tim System"
- the "MAGNETOM Trio a Tim System"

is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. These images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

- The "MAGNETOM Espree"
- the "MAGNETOM Avanto"
- the "MAGNETOM Symphony a Tim System"
- the "MAGNETOM Trio a Tim System"

may also be used for imaging during interventional procedures performed with MR compatible devices such as, in room display and MR safe biopsy needles.

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Concurrence of CDRH, Office of Device Evaluation

Prescription Use

OR

Over-The-Counter Use

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052164